

NO. 13-16833

**IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

Pharmaceutical Research And Manufacturers of America, *et al.*,

Plaintiffs-Appellants,

v.

Alameda County, *et al.*,

Defendants-Appellees.

**ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
HONORABLE RICHARD SEEBORG
NO. C 12-6203 RS**

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RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Appellants are nonprofit corporations without publicly traded stock or parent corporations.

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JURISDICTIONAL STATEMENT

This Court has appellate jurisdiction under 28 U.S.C. § 1291, and the district court had jurisdiction under 28 U.S.C. § 1331. The district court ruled on August 28, 2013, and Appellants filed a timely notice of appeal. Fed. R. App. P. 4; ER 60.

ISSUE PRESENTED

Whether Alameda County's "Safe Drug Disposal Ordinance," which shifts the entire responsibility and cost of local unused pharmaceutical collection efforts onto the producers of pharmaceutical products, violates the "dormant" aspect of the Commerce Clause of the U.S. Constitution. The Ordinance is reproduced in Appellants' Addendum, as well as in the Excerpts of Record, starting at ER 65.

STATEMENT OF THE CASE

Appellants filed this action in the Northern District of California. Trial Docket No. 1 ("Tr. Dkt."). The parties then voluntarily entered into joint stipulations for the purposes of resolving cross-motions for summary judgment. Tr. Dkt. 28. After the parties filed cross-motions for summary judgment, Tr. Dkt. 27, 31, the district court on August 28, 2013, entered an opinion and order granting summary judgment to Appellees and denying summary judgment to Appellants. Tr. Dkt. 40-41. Appellants then timely appealed. Tr. Dkt. 42. After Appellants filed a motion for expedition and Appellees filed a motion in opposition, this Court

partially granted the motion for expedition and established an accelerated schedule for briefing and argument. Appellate Docket (“App. Dkt.”) No. 6.

STATEMENT OF FACTS

The Ordinance, enacted by Alameda County’s Board of Supervisors in July 2012, requires any prescription drug producer that may have any product distributed in Alameda County to engage in an expensive and risky effort to collect and safely dispose of *all* the County’s unused prescription medicines. The Ordinance exempts all local entities—local pharmacies and consumers—from any such responsibilities or costs for establishing and running these programs, thus ensuring that all costs of the Alameda program will be paid for by interstate manufacturers and their customers nationwide.¹

¹ Appellants believe that in-home disposal, where unwanted pharmaceutical products are discarded with the household trash, is an environmentally preferable way to dispose of unwanted medicines. *See, e.g.,* Lial Tischler et al., *Landfill Disposal of Unused Medicines Reduces Surface Water Releases*, 9 INTEG. ENV. ASSESSMENT & MGMT. 142 (2012). Appellants also believe that in-home disposal minimizes the potential that collection kiosks, bins and other handling facilities used in collection programs would become a target for thieves and others who might wish to divert unused medicines for improper or illegal purposes. *See, e.g.,* Jennie Olson, *Ex-Washington Co. Deputy Convicted of Stealing from Drug “Take-Back” Bin*, ABC, available at <http://kstp.com/news/stories/S3209866.shtml>. Nonetheless, appellants recognize that local and/or state officials may believe that other disposal programs, such as the take-back program envisioned for Alameda County, better meets their local needs. Appellants have no objection to Alameda County running a program like the one at issue here but do object when local officials seek to shift the responsibility of operating the program or the cost of the

I. The Interstate Pharmaceutical Delivery System

The prescription pharmaceuticals covered by the Ordinance are articles of interstate commerce. Indeed, the parties entered into joint stipulations in the district court, and those stipulations demonstrate that 100% of prescription medicines sold in Alameda County arrived there through interstate commerce. *See* Joint Stipulations, ER 81-88 (“Stipulations”) ¶¶ 14-24.

According to the stipulations, the U.S. Food and Drug Administration’s electronic database records indicate the presence of only twenty-four facilities in Alameda County registered to manufacture prescription medicines. *See* Stipulation ¶ 14, ER 84. Nineteen of those facilities do not actually manufacture prescription drugs. *Id.* ¶ 15. One of those facilities manufactures products not commercially distributed in the United States. *Id.* ¶ 16. And the remaining four facilities, which are operated by Plaintiffs’ members Bayer and Impax Laboratories, *see id.*, “are shipped outside the County before being distributed back into Alameda County,” *id.* ¶ 23, ER 85. Confirming that 100% of in-county prescription medicines crossed county lines, “[n]either the County nor Plaintiffs are aware of any prescription drugs distributed in Alameda County that arrive there via intra-County

(continued...)

program to consumers who live in other parts of the country and who receive no benefit from the Alameda program.

distribution channels as opposed to arriving there via distribution channels that cross the County's borders." *Id.* ¶ 24, ER 85.

II. Deliberations By The Alameda County Board of Supervisors

Before and after enacting the Ordinance, Alameda County had operated (and continues to operate) its own government-funded pharmaceutical collection program with over two dozen collection sites. In 2011 and 2012, however, the County began to consider shifting the entire cost of operating local collection efforts onto pharmaceutical producers. This effort initially met opposition from local pharmacies, resulting in their express exemption from regulatory burdens.

Indeed, almost every comment introduced by the Ordinance's sponsor, most from governmental sources, emphasized that the Ordinance would shift costs away from local businesses and taxpayers. *See* Letter from Alameda County Health Care Services Agency, Agenda and Addendum for the February 28, 2012, Regular Meeting of the Alameda County Board of Supervisors (Exhibit C),² ER 188 available at <http://www.acgov.org/board/broadcast.htm> ("The safe disposal of pharmaceuticals should be considered a societal need for which the cost to provide should not fall to local government."); Letter from Union Sanitary District, ER 176 ("The burden of cost should not fall on local agencies or the ratepayers."); Letter

² These exhibits (Ex.) were attached to Appellants' Motion for Summary Judgment, *see* Tr. Dkt. 27, and are reproduced in the Excerpts of Record.

from Central Contra Costa Sanitary District, ER 178 (“Local governments, such as ours, . . . should not bear the cost of their collection and proper disposal nor should our ratepayers.”); Letter from Save the Bay, ER 177 (asserting that “the costs of [safe disposal] should not fall on local government”); Letter from the Mayor of Emeryville, ER 175 (same); Letter from Sacramento Municipal Services Agency, ER 180 (same); Letter from Teleosis Institute, ER 181 (same); Letter from City of Livermore Water Resources Division, ER 183 (“We and our rate payers . . . should not bear the cost and responsibility of their collection and proper disposal.”).

Similarly, a representative of the Department noted at a Board meeting that the County’s existing collection sites “are paid for by taxpayers or ratepayers,” and argued that “the cost shouldn’t fall on local government.” Recording at 11:35-12:45, ER 192 (Board Session of February 28, 2012), Tr. Ex. E, available at <http://www.acgov.org/board/broadcast.htm>; *see also id.* at 19:55-20:10 (representative of the Alameda County Waste Management Authority: “the cost of the safe disposal of pharmaceuticals should not fall on local government”).

As aptly summarized by Nathan A. Miley, the Ordinance’s principal sponsor and President of the Board of Supervisors, the Ordinance’s drafters believed that the only thing “wrong” with the preexisting, “publicly-funded [collection] program” in Alameda County was “that the taxpayers pay for it.” *See* KQED Radio Interview, “Alameda County Poised to Require Companies to Take Back Unused

Drugs” (July 23, 2012), Ex. D, ER 190 available at http://www.kqed.org/news/story/2012/07/23/103330/alameda_county_poised_to_require_companies_to_take_back_unused?category=bay+area.

III. Alameda County’s Ordinance and Regulations

The Ordinance requires any “Producer” of “Covered Drugs” to operate collection programs in Alameda County. Addendum; *see also* ER 65.³ The term “Producer” is defined to include three distinct entities. First, the term includes all entities that manufacture a “Covered Drug” and sell it in Alameda County “under that Person’s own name or brand.” § 6.53.030.14(i). Second, if no person falls within the first criterion for a particular Covered Drug, then the term “Producer” includes the “owner or licensee of a trademark or brand under which the Covered Drug is sold or distributed in Alameda County.” § 6.53.030.14(ii). Third, if there is no person who falls within either of the first two criteria, then “Producer” includes “the Person who brings the Covered Drug into Alameda County for sale or distribution.” § 6.53.030.14(iii). There are exceptions for pharmacies and other retailers that dispense prescription drugs to patients. § 6.53.030.14. The term “Covered Drug” is initially defined broadly to include “all drugs as defined in 21 U.S.C. § 321(g)(1) of the Federal Food, Drug and Cosmetic Act,” “including both

³ The Ordinance is attached as an Addendum and copied in the Excerpts of Record starting at ER 65. All Ordinance citations are of the form “§ [section].”

brand name and Generic Drugs.” § 6.53.030.3. But the definition of “Covered Drugs” also includes a number of exemptions, perhaps the broadest of which is for “nonprescription drugs.” *Id.*

The Ordinance envisions two types of program. § 6.53.040A.1. First is a program run by an individual Producer. Second is a product “stewardship organization” formed by a group of Producers. A jointly funded program must involve a “fair and reasonable manner for allocating the costs” such that each Producer is charged a portion of the costs related to its contribution to covered drugs sold in the County. § 6.53.050.A.13. All programs must provide collection options that are “convenient and adequate to serve the needs of Alameda County residents.” § 6.53.050.A.3. This standard is enforced in Alameda’s sole discretion, and the Ordinance supplies no specific guideposts for compliance.

Every Producer’s collection program must accept and dispose of *all* Covered Drugs, no matter who manufactured them, unless excused from that comprehensive obligation by the Alameda Department of Environmental Health (“the Department”). § 6.53.050.A.1. Kiosks specifically targeting controlled substances must be provided if a County law enforcement agency agrees to provide space for such kiosks. § 6.53.050.A.11. Collected items must be disposed of by incineration at a medical waste or hazardous waste facility. § 6.53.060.B.

In addition, Producers must: provide informational materials for retailers to distribute to consumers; provide signage, advertising, and other promotional materials; establish a website; and operate a toll-free call system for consumers to learn how the program operates. § 6.53.070. These and other “education[al]” and “outreach” efforts will be carefully regulated. § 6.53.050(A)(8); Alameda Regulations, §§ 7(A)(ii)-(iii), 8(A)(vi-vii), ER 142, 145. These materials must address the “importance of promptly and properly disposing of Unwanted Products” and “How to properly dispose of Unwanted Products.” *Id.* § 8(A)(vii). Thus, Alameda intends to compel speech to “educate” consumers about the County’s views on “proper” drug disposal.

Alameda has granted itself broad discretion to impose its own view of the best collection policies. For example, the Department may reject a proposed plan that is not “adequate to serve the needs of Alameda County residents.” *Id.* § 8(A)(i), ER 145. The Department may also consider whether collection plans establish adequate management and security practices. *Id.* § 8(A)(ii)-(iii), ER 145. Indeed, many decisions are simply left to the Department’s “discretion.” *E.g., id.* §§ 5(B)(iii), 8(B), 9, 10(A), 10(F), 11, 13(C), 13(D), 16, 17(C), ER 137 *et seq.*

Plaintiffs estimate that compliance with the Ordinance will impose startup costs of approximately \$1,100,000 and annual costs of approximately \$1,200,000, assuming that all covered entities join a single collection program and that local

pharmacies supply free space for collection kiosks. *See* Stipulation ¶ 27, ER 86. Further, each Producer must compensate Alameda for the Ordinance's administrative costs by paying fees set by the Department. § 6.53.100. These exactions include the cost of inspectors involved in "monitoring Plan compliance." Alameda Regulations § 12, ER 150. Defendants estimate that the annual administrative costs will total about \$200,000. Stipulation ¶ 28, ER 86. The Department may also charge a civil penalty up to \$1,000 per day for any violation. The Ordinance prohibits a Producer or any other person from charging a "specific point-of-sale fee to consumers to recoup the costs" of establishing or operating a collection program mandated under the Ordinance. § 6.53.040.B.3.

Collection plans were originally due to the Department on July 1, 2013, but that deadline was initially extended until November 1, 2013. Alameda Regulations § 6(A), ER 142. The County has now adopted an additional extension of the deadline until May 1, 2014. Within 180 days of each plan submission, the Department will conduct a plan-review hearing. § 6.53.050.B.2-3. A rejected plan must be revised within 60 days, at which time Alameda may give approval, direct additional revisions, or "impose" its own plan. *Id.*

IV. Litigation In The District Court

Appellants brought the present action under the dormant aspect of the Commerce Clause of the U.S. Constitution, seeking declaratory and other relief.

Appellants and Appellees then entered joint stipulations for the purposes of summary judgment and filed cross-motions for summary judgment.

Appellants' principal argument in the district court was that the Ordinance "violates the Commerce Clause *per se*" because it "directly regulates interstate commerce." *NCAA v. Miller*, 10 F.3d 633, 638 (9th Cir. 1993). The Ordinance "directly regulates" in that it imposes on covered producers the entire responsibility and cost of administering a collection program. And the Ordinance regulates "interstate commerce" because, in light of the joint stipulations, the only way of incurring burdens under the Ordinance is to produce a medicine that has arrived in Alameda County through interstate commerce. Citing the joint stipulations and the legislative history, Appellants contended that the Ordinance is an impermissible direct regulation in both its effect and its purpose. Appellants also argued that the Ordinance is *per se* unconstitutional because it discriminates against interstate commerce and favors local interests.

Recognizing that all prescription pharmaceutical products are articles of interstate commerce, the County focused on the dormant Commerce Clause's prohibition against local protectionism. The Ordinance, the County observed, was not designed to advantage local industry over outside economic competition. And the County further contended that only laws that discriminate between in-county and out-of-county companies could transgress the dormant Commerce Clause

doctrine. The County accordingly argued that it was legally irrelevant, as well as a mere coincidence, that most or all covered producers were physically located outside Alameda County. Finally, the County asserted that it was justified in shifting all collection costs onto producers because only by doing so could the County conserve its own “sparse resources.”

V. The District Court Decision

The district court denied Appellants’ motion for summary judgment and granted summary judgment to Alameda County.

At the outset, the district court correctly recognized that the Ordinance was “a ‘first in the nation’” method of “addressing concerns arising from the disposal of unused prescription drugs.” District Court Opinion (Op.) at 1, ER 1. In particular, the Ordinance was unprecedented in that it was specifically “crafted to place the entire cost of such programs on the producers.” *Id.* To wit, “retail pharmacies are exempt” from pharmaceutical collection responsibilities, “and sellers are prohibited from passing the expense directly to Alameda County consumers by adding a fee at the point of sale.” *Id.*

The district court then recognized that, under this Court’s precedents, there are three distinct ways in which a local law can give rise to a “*per se* violation” of the dormant Commerce Clause. *Id.* at 8, ER 8. In particular, a local law is *per se* unconstitutional “if it, ‘1) directly regulates interstate commerce; 2) discriminates

against interstate commerce; or 3) favors in-state economic interests over out-of-state interests.”” *Id.* (quoting *NCAA*, 10 F.3d at 638).

The district court began its analysis by focusing on the second and third *per se* categories, which respectively pertain to discrimination against interstate commerce and local favoritism. According to the district court “the second and third prongs both contain an element of discrimination—i.e., that a challenged regulation favors local commerce over interstate commerce or in-state entities over out-of-state entities.” *Id.* The district court held that the necessary “element of discrimination” was absent here because the Ordinance “is indisputably not being visited on out-of-state producers as a means of favoring in-state producers.” *Id.*

The district court then turned back to the first *per se* category, noting that “discrimination and economic protectionism are not the sole tests.” *Id.* at 9, ER 9 (quoting *NCAA*, 10 F.3d at 638). Nonetheless, the district court found no direct regulation of interstate commerce under the first prong because the Ordinance “applies to producers who elect to sell their products within Alameda County, regardless of where the producers are based or the product originates.” *Id.* Further, the district court asserted, “[n]othing in the Ordinance will require, as a practical matter, any producer to alter its manner of doing business in any jurisdiction outside Alameda County.” *Id.* The district court also noted that, while the Ordinance must be tested by its practical effect, “the happenstance that most

producers of prescription drugs are located outside Alameda County” did not render the Ordinance unconstitutional under the dormant Commerce Clause.

STANDARD OF REVIEW

This Court reviews orders of summary judgment *de novo*.

SUMMARY OF ARGUMENT

The Ordinance is a quintessential example of a “direct regulation” that impermissibly burdens interstate commerce. *Kleenwell Biohazard Waste & Gen. Ecology Consultants, Inc. v. Nelson*, 48 F.3d 391, 396 (9th Cir. 1995) (“*Kleenwell*”). It is certainly *direct*—it requires the affected companies to enter Alameda and assume the responsibilities and associated costs of administering a collection program that heretofore has been part of Alameda’s traditional local government function of waste disposal. It also regulates *interstate commerce*, because the Ordinance’s sole criterion for imposing these duties and costs is that a manufacturer has sold a product into interstate commerce and, through a complex chain of wholesalers and intermediaries, some of its product has become available for sale or to be dispensed in Alameda. Requiring that companies administer and fund a local waste-disposal program as a condition for permitting their goods to be sold in the County is necessarily a regulation of, and burden on, interstate articles of commerce. And all agree that 100% of the affected prescription medicines cross County lines. Stipulations ¶¶ 23, 24, ER 85. Thus, like a tariff, the Ordinance

imposes costs on the delivery of interstate goods and also leverages that interstate commerce to impose Alameda's governmental responsibilities on interstate actors.

The Ordinance is also unconstitutional under the two subsidiary tests that this Court has articulated for assessing impermissible "direct" regulations and burdens. First, the Ordinance is a forbidden direct regulation and burden because its "primary purpose" is to "regulate commerce . . . in order to benefit local interests," by shifting the costs and responsibilities of a local waste collection program to the interstate market. *Kleenwell*, 48 F.3d at 396. This purpose is made clear by the Ordinance's plain text, as well as its legislative history. There is simply no plausible explanation for the Ordinance's design other than to shift local costs onto outsiders.

Second, the Ordinance has the impermissible effect of "directly affect[ing] transactions that take place across [County] lines" and outside of Alameda *S.D. Myers, Inc. v. City & Cnty. of San Francisco*, 253 F.3d 461, 467 (9th Cir. 2001). The "practical effect" of the Ordinance is to attach the costs of the take-back program to pharmaceuticals delivered across Alameda's border. *Id.* ("[T]he 'practical effect' of a challenged statute is 'the critical inquiry' in determining whether that statute constitutes direct regulation"). Moreover, the Ordinance regulates transactions wholly outside the County's borders by requiring affected

companies to get into an entirely new line of business—waste disposal—and to establish a presence for their new business in Alameda.

In its decision below, the district court effectively ignored the Commerce Clause’s prohibition on direct regulation. Instead, the district court found that the Ordinance did not discriminate against out-of-county *companies*. See Op. 9, ER 9 (“Nothing in the structure of the Ordinance targets producers on the basis of their location”). But the Commerce Clause protects interstate *commerce*, not interstate companies. In making protectionist discrimination against outside *companies* the *sine qua non* of a dormant Commerce Clause violation, the district court erred by failing to recognize that the Clause protects the flow of interstate goods.

Finally, even if it is not a *per se* violation, the Ordinance unjustifiably burdens interstate commerce because a government-funded pharmaceutical collection program would be just as effective as a program run by Appellants, without burdening interstate trade.

If the Ordinance were permissible, then localities could require interstate newspapers to conduct local paper recycling programs wherever their newspapers are sold or order interstate wine producers to engage in glass recycling wherever their bottles are distributed. Local politicians would be able to give their constituents something for nothing, while shifting all the costs onto unrepresented

consumers and businesses nationwide. The dormant Commerce Clause doctrine does not permit that result.

ARGUMENT

I. The Commerce Clause Imposes a *Per Se* Prohibition On Local Laws That Directly Regulate Interstate Commerce

The Commerce Clause of the Constitution affords Congress the authority to “regulate commerce . . . among the several states.” U.S. CONST. art. I, § 8. The “negative” aspect of this Clause—known as the “dormant Commerce Clause” doctrine—holds that the Clause “‘by its own force’ prohibits certain state actions that interfere with interstate commerce.” *Quill Corp. v. North Dakota*, 504 U.S. 298, 309 (1992) (quoting *S.C. State Highway Dep’t v. Barnwell Bros., Inc.*, 303 U.S. 177, 185 (1938)). This “dormant” or “negative” aspect of the Commerce Clause has a single overriding purpose: to preempt parochial regulations that burden interstate trade and so foster “economic Balkanization” of the national market. *Oregon Waste Sys., Inc. v. Dep’t of Env’tl. Quality of State of Or.*, 511 U.S. 93, 98 (1994) (internal quotation marks omitted).⁴

⁴ This principle applies equally to local governments like Alameda County. See, e.g., *C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 394 (1994) (“[L]ocal governments may not use their regulatory power to favor local enterprise”); *Dean Milk Co. v. City of Madison*, 340 U.S. 349 (1951) (invalidating ordinance enacted by Madison, Wisconsin); *BFI Med. Waste Sys. v. Whatcom Cnty.*, 983 F.2d 911, 913 (9th Cir. 1993) (“[A] State (or one of its political subdivisions) may not avoid the strictures of the Commerce Clause by

Thus, the dormant Commerce Clause preempts local measures that unjustifiably “burden the interstate flow of articles of commerce.” *Id.* As the Supreme Court has repeatedly stated in dormant Commerce Clause cases, “this Nation is a common market in which state lines cannot be made barriers to the free flow of both raw materials and finished goods.” *Hughes v. Alexandria Scrap Corp.*, 426 U.S. 794, 803 (1976).

Dormant Commerce Clause jurisprudence respects and reflects the dual roles of the federal and state governments regarding interstate commerce. The federal government is given “plenary” authority over such commerce, *Oregon Waste*, 511 U.S. at 98, such that a state law has impermissibly “invad[ed] the province of Congress” if it directly burdens or regulates such commerce. *Kleenwell*, 48 F.3d at 398. On the other hand, however, the Clause’s grant of plenary federal power over interstate power did *not* divest state and local governments of their traditional police power to regulate and tax activities or products within their jurisdiction—including products arising from out of state—and such exercises of the police and

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curtailing the movement of articles of commerce through subdivisions of the State, rather than through the State itself.” (quoting *Fort Gratiot Sanitary Landfill, Inc. v. Mich. Dep’t of Natural Res.*, 504 U.S. 353, 361 (1992)).

taxing power can have an indirect effect on the flow or price of interstate goods. *D.H. Holmes Co. v. McNamara*, 486 U.S. 24, 29-30 (1988).

In order to reasonably reconcile the state’s police power over intra-state transactions and plenary federal authority over interstate commerce, the critical question in dormant Commerce Clause cases is whether the local regulation constitutes a neutral exercise of the police power to protect the local citizenry’s health and safety, with only incidental effects on interstate commerce, or whether the regulation is an effort to secure local economic advantage by constricting or burdening interstate commerce:

The distinction between the power of the State to shelter its people from menaces to their health or safety and from fraud, even when those dangers emanate from interstate commerce, and its lack of power to retard, burden or constrict the flow of such commerce for their economic advantage, is one deeply rooted in both our history and our law.

D.H. Holmes, 486 U.S. at 29-30 (quoting *H. P. Hood & Sons, Inc. v. DuMond*, 336 U.S. 525, 533 (1949)); see also *Nat’l Ass’n of Optometrists & Opticians v. Harris*, 682 F.3d 1144, 1148 (9th Cir. 2012) (“*NAOO*”). The Supreme Court accordingly asks whether a law has “extend[ed] the town’s police power beyond its jurisdictional bounds,” *C & A Carbone, Inc. v. Town of Clarkstowne*, 511 U.S. 383, 393 (1994), and “invade[d]” the federal sphere by retarding, burdening or constricting interstate commerce, or, conversely, whether the regulation is

“designed to address a legitimate local concern [that] incidentally affects interstate commerce.” *Kleenwell*, 48 F.3d at 398.

Specifically, the Supreme Court has established a “two-tiered” analysis of local regulation, as this Court has repeatedly noted. *S.D. Myers*, 253 F.3d at 466; *NCAA*, 10 F.3d at 638. First, with respect to legitimate efforts to protect the local citizenry’s health and welfare, the courts will apply a relatively deferential analysis. When a local “statute has only indirect effects on interstate commerce and regulates evenhandedly,” courts examine “whether the State’s interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits.” *NCAA*, 10 F.3d at 638 (quoting *Healy v. Beer Institute*, 491 U.S. 324, 337 n.14 (1989) (internal quotation marks omitted)); *see also Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).

In contrast, when a regulation’s effect on interstate commerce is not an incidental consequence of neutral and genuine local regulation, then a “virtually *per se*” rule of invalidity applies. *Oregon Waste*, 511 U.S. at 99. Specifically, when a local law (i) “directly regulates” or “directly burdens” interstate commerce, (ii) “discriminates against interstate commerce,” or (iii) “favors in-state economic interests over out-of-state interests,” then the measure “violates the Commerce Clause *per se*, and we must strike it down without further inquiry.” *NCAA*, 10 F.3d at 638; *Pacific Merchant Shipping Ass’n v. Goldstene*, 639 F.3d 1154, 1177 (9th

Cir. 2011) (“directly burdens”). If a law falls into “any of these” three *per se* categories, then it is invalid. *Id.* This case essentially involves the first *per se* category, which forbids local laws that directly regulate or burden interstate commerce.

Under that first *per se* category, this Court has applied two subsidiary tests for evaluating whether a local law imposes an impermissible “direct regulation”—or, equivalently, a “direct burden”—on interstate commerce. *See Pacific Merchant*, 639 F.3d at 1177; *see also Kleenwell*, 48 F.3d at 395-96. First, a local measure is unconstitutional when its “*central* purpose is to regulate commerce, usually in order to benefit local interests.” *Kleenwell*, 48 F.3d at 395-96. Second, a local law is an impermissible direct regulation when it “directly affects transactions that take place across state lines or entirely outside of the state’s borders.” *S.D. Myers*, 253 F.3d at 467 (internal quotation marks omitted); *see also Valley Bank of Nev. v. Plus Sys., Inc.*, 914 F.2d 1186, 1190 (9th Cir. 1990) (“Such a statute is invalid *per se*” (internal quotation marks omitted)). As explained below, the Ordinance plainly constitutes a direct regulation of and a burden on interstate commerce, and fails both of these specific tests.

II. The Ordinance is a *Per Se* Violation Of The Dormant Commerce Clause Because Its Primary Purpose And Effect Are To Regulate And Burden Interstate Commerce

As noted, a local law improperly burdens interstate commerce if it “directly regulates” or “burdens” interstate commerce, *NCAA*, 10 F.3d at 638, which is established if, *inter alia*, it has the “primary purpose” of “regulat[ing] commerce, usually in order to benefit local interests,” *Kleenwell*, 48 F.3d at 396, as well as if it “directly affects transactions that take place across [county] lines or entirely outside of the [county’s] borders.” *S.D. Myers*, 253 F.3d at 467 (internal quotation marks omitted). The Ordinance plainly violates the general “direct burden” or “regulation” prohibition, as well as both of this Court’s specific formulations of that prohibition.

A. The Ordinance Directly Regulates And Burdens Interstate Commerce.

1. *Direct Regulation.* This case does not present the sometimes difficult issue of the extent to which the Commerce Clause preempts local police-power regulations designed to improve safety or the environment. *E.g.*, *Pacific Merchant*, 639 F.3d at 1178; *Kleenwell*, 48 F.3d 391. In these more typical dormant Commerce Clause cases, the state or local government has exercised its police power to protect the local citizenry by regulating or banning harmful, morally objectionable or deceptive products or practices. *See, e.g.*, *Association Des Eleveurs De Canards Et D’Oies Du Quebec v. Harris*, 729 F.3d 937, 948 (9th

Cir. 2013) (upholding a law prohibiting the sale of foie gras resulting from the morally objectionable forced feeding of ducks); *Pacific Merchant*, 639 F.3d at 1178 (upholding California fuel use regulations as they applied to sea-going vessels in transit off the California coast); *Kleenwell*, 48 F.3d 391 (upholding a law requiring out-of-state business to obtain certificates of public convenience and necessity before collecting and transporting medical waste).

In these cases, as noted, the central question is whether the statute furthers a “legitimate” exercise of traditional state responsibility. *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986). The threshold test for such legitimacy is whether the purported police power law treats local companies better than out-of-state companies. If so, this (1) undermines the police power justification for the law (if the challenged regulation really is directed at perceived deficiencies in the *product*, it would impose the same restrictions on local companies providing that product); (2) raises the strong suspicion that the legislature is favoring those voters to whom they are accountable over foreign entities; and (3) distorts the free flow of interstate goods by favoring native producers. See *McGoldrick v. Berwind-White Coal Mining Co.*, 309 U.S. 33, 45 n.2 (1940); *Raymond Motor Transp., Inc. v. Rice*, 434 U.S. 429, 444 n.18 (1978); *West Lynn Creamery v. Healy*, 512 U.S. 186, 200 (1994); *Minnesota v. Clover Leaf*

Creamery Co., 449 U.S. 456, 473 n.17 (1981); *S.C. State Hwy. Dep't*, 303 U.S. at 187.

Conversely, if the law is an even-handed exercise of the police power, then it will often be upheld because (1) the Commerce Clause did not strip states of their power to regulate “in areas of traditional local concern,” *Kassel v. Consolidated Freightways Corp. of Del.*, 450 U.S. 662, 678 (plurality opinion); (2) the statute’s even-handedness strongly suggests that it is not an impermissible effort to favor local interests through “shift[ing] the costs of regulation” to the interstate market, *United Haulers Ass’n, Inc. v. Oneida-Herkimer Solid Waste Management Authority*, 550 U.S. 330, 345 (2007); and (3) there is little or no disruption of the interstate market through an uneven playing field, since all companies are subject to the same restrictions. *See Pike*, 397 U.S. at 142 (“Where the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits.”).

This case is quite different and poses a less common, but far more obvious Commerce Clause violation. Rather than the local government exercising its police power, where the legitimacy of that exercise is examined by looking at whether domestic companies are preferred, the Ordinance here serves no police

power function and is facially directed at burdening the interstate market by imposing on that market all the costs and responsibilities of developing and operating Alameda's drug disposal program, to benefit local interests.

Through the Ordinance, Alameda is not *exercising* its police power to help the environment or citizens' health. Rather, it is *transferring* its traditional police power responsibility of waste disposal to interstate actors, solely on the basis that one of their interstate products is sold in Alameda, after being delivered there through an interstate distribution chain. *Cf. United Haulers*, 550 U.S. at 344 ("For ninety years, it has been settled law that garbage collection and disposal is a core function of local government in the United States." (internal quotation marks and citation omitted)). The Ordinance did not *establish* a drug collection program; the County already had one (which still continues). *See supra* p. 4. And, of course, Alameda did not require drug manufacturers to operate the collection program because it thought that those manufacturers had a greater expertise in waste disposal than the County itself; indeed, the County has never disputed that its officials would and could perform drug collection and disposal as well as the Appellants. Thus, Alameda's environment and water would be in precisely the same condition if collection were to continue to be performed by the County, rather than transferring that responsibility to Producers.

That being so, the Ordinance cannot serve any environmental or other police power purpose. Its only conceivable—and candidly avowed—purpose was to impose that regulatory burden on and shift the associated costs to out-of-state pharmaceutical producers, which is why the Ordinance’s sponsors called it an unprecedented, “first-in-the-nation” law. Because it does not serve any health or environmental goals that would not be fully accomplished absent the transfer of collection and disposal responsibility to drug Producers, the Ordinance cannot be an exercise of the police power with an “*incidental*” effect on interstate commerce, but is necessarily an effort to directly regulate and burden the interstate market by transferring Alameda’s police power responsibilities.

Moreover, the Ordinance on its face is a direct regulation of interstate commerce, since it regulates Producers whose only connection to Alameda is such interstate commerce, and does so by compelling those out-of-state Producers to establish a physical presence in Alameda in order to perform a waste disposal function wholly different than their interstate manufacturing business. To be clear, local governments have broad authority (absent federal preemption) to regulate and tax the sales and distribution of products within their jurisdiction, regardless of whether those goods are interstate products. *E.g.*, *Black Star Farms LLC v. Oliver*, 600 F.3d 1225 (9th Cir. 2010). But here, Alameda is not regulating the sale or distribution of harmful or morally objectionable products; it obviously *supports* the

sales of Appellants' medicines because they benefit those Alameda citizens in need of them. Rather than regulating or banning sales of dangerous interstate *products*, the County is *leveraging* those sales to regulate interstate *producers*. Alameda uses a local sale at the end of the interstate distribution chain to regulate producers at the beginning of that chain, even though Alameda has no other jurisdiction over those Producers and the Producers have no other nexus to Alameda. While, again, localities generally have broad authority to regulate sales at the end of the distribution chain if they occur within their jurisdiction, and to regulate products at the beginning of that chain if they are manufactured within the jurisdiction, they have no authority to exploit a sale within their jurisdiction to coerce manufacturers to undertake affirmative steps to benefit the local jurisdiction.

This is because the distribution chain is simply another name for "interstate commerce." Using the final transaction at the end of "interstate commerce" to directly regulate those who put the product into interstate commerce cannot be described as anything other than direct regulation of interstate commerce.

This is particularly true here because the Ordinance's regulatory mandate requires external Producers to, for the first time, establish a physical presence in Alameda to perform a *disposal* function that is unrelated to their *manufacturing* business mission, but at the core of Alameda's governmental mission. The Ordinance thus requires Producers to internally develop a new waste disposal unit

or to create a new, joint start-up which contracts with entities that have relevant waste disposal expertise. In either event, the Ordinance will inevitably and necessarily mandate complex activity and due diligence by Producers outside Alameda and/or out-of-Alameda contracts between non-Alameda manufacturers and non-Alameda waste disposal companies.

Worse still, the Producers must (often for the first time) establish a physical presence and conduct transactions in Alameda, in order to implement the take-back programs. Alameda would obviously violate the Commerce Clause if it required all Producers to establish *drug production* facilities or services in Alameda solely because one of their medicines had been distributed there (even though the requirement would mandate only the production activity that Producers excel at and would only indirectly benefit Alameda). *A fortiori*, it cannot impose the Ordinance's requirement of creating Alameda *drug disposal* facilities and services, since that is wholly outside their expertise and directly benefits the County by relieving it of a core waste disposal responsibility. For these reasons, as detailed below, the Ordinance's "extra-territorial effect" on Appellants' business activities conducted outside of Alameda is far more direct, intended and intrusive than that involved in laws invalidated by this Court and the Supreme Court because of such out-of-jurisdiction consequences. *See infra* pp. 49-50.

In sum, Alameda's attempt to regulate interstate actors based purely on interstate commerce violates the most fundamental *jurisdictional* barrier created by the Constitution's grant of plenary federal power over interstate commerce; *i.e.*, a prohibition against local jurisdictions "exceeding their jurisdictional bounds" and "entering the federal domain" by using the arrival of one interstate product to regulate unconnected activity by the foreign manufacturer of that product. *See, e.g., D.H. Holmes Co.*, 486 U.S. at 29-30. Moreover, as we explain below, because that direct regulation imposes substantial costs on Appellants, the Ordinance also creates precisely the core *economic* evil that the Commerce Clause sought to prevent by stripping states of the ability to burden or regulate interstate commerce.

2. *Direct Burden.* The Ordinance also imposes a direct economic burden on the flow of interstate goods, for the wholly illegitimate purpose of "benefit[ing] local interests" by shifting the costs of Alameda's disposal responsibility and local government program from the County's consumers and taxpayers to the interstate market. *Kleenwell*, 48 F.3d at 395-96. Rather than financing the collection and disposal program from general local tax revenues—or a special waste disposal tax or fee attached to Alameda pharmaceutical sales—the Ordinance imposes *all* of the

program's costs on pharmaceutical manufacturers (even requiring them to compensate Alameda for its *regulation* of themselves).⁵

The substantial economic costs of forming and operating collection programs is triggered, in “practical effect,” exclusively by the delivery of covered pharmaceuticals across Alameda's county lines. *S.D. Myers*, 253 F.3d at 467. Thus, although the Supreme Court has repeatedly stated that “this Nation is a common market in which state lines cannot be made barriers to the free flow of . . . goods,” *Hughes*, 426 U.S. at 803, Alameda has made its county line a barrier to the free flow of pharmaceuticals, by imposing the economic costs and responsibilities of conducting a collection program on those manufacturers whose products are shipped across that line.

a. The only (and avowed) purpose of imposing these costs on the delivery of interstate goods is cost-shifting. Since, as noted, *transferring* collection and disposal responsibilities to Appellants serves no safety or environmental purpose, its only purpose is to shift the cost of that regulation from local taxpayers (and voters) to foreign consumers and producers in the interstate market. So

⁵ Underscoring that the Ordinance forces Producers to enter the County and undertake government responsibilities, Producers must engage in certain Alameda-approved “educational” programs, thereby becoming mouthpieces for the County. See § 6.53.050(A)(8); Alameda Regulations §8(A)(vi), ER 145. *But see CTIA—The Wireless Ass’n v. San Francisco*, No. 11-17773 (9th Cir. Aug 9, 2012).

“constrict[ing] the flow of [interstate] commerce for [local] economic advantage” is the quintessential problem that the dormant Commerce Clause was designed to prevent. *D. H. Holmes*, 486 U.S. at 29-30. Consequently, this Court has squarely stated that a law has an impermissible “direct burden” on interstate commerce if, under the law, the locality “would be able to shift the tax burden to out-of-state . . . producers.” *Nat’l Meat Ass’n v. Deukmejian*, 743 F.2d 656, 661 (9th Cir. 1984).

As the Supreme Court and this Court have frequently noted, local laws that transfer regulatory costs *away from* local interests to whom the enacting governments are accountable and *toward* unrepresented external entities give rise to the “recognized danger that, to the extent that the burden falls on economic interests without the state, it is not likely to be alleviated by those political restraints which are normally exerted on legislation where it affects adversely interests within the state.” *McGoldrick*, 309 U.S. at 45 n.2; *see also West Lynn Creamery*, 512 U.S. at 200; *Clover Leaf Creamery*, 449 U.S. at 473 n.17; *S.C. State Hwy. Dep’t.*, 303 U.S. at 187; *Pacific Nw. Venison Producers v. Smitch*, 20 F.3d 1008, 1012-13 (9th Cir. 1994) (local exceptions “undermine the assumption that the State’s own political processes will act as a check on local regulations that unduly burden interstate commerce”); *Conservation Force, Inc. v. Manning*, 301 F.3d 985, 998 (9th Cir. 2002) (citing JOHN HART ELY, *DEMOCRACY AND DISTRUST: A THEORY OF JUDICIAL REVIEW* 77-84 (1980)); LAURENCE H. TRIBE, *AMERICAN*

CONSTITUTIONAL LAW 105 (3d ed. 2000) (discussing “the recognition implicit in the Commerce Clause that state and local lawmakers are especially susceptible to pressures that may lead them to make decisions harmful to the commercial and other interests of those who are not constituents of their political subdivisions”).

This is why “dormant Commerce Clause cases often find discrimination against interstate commerce when a State shifts the costs of regulation to other States.” *United Haulers*, 550 U.S. at 345; *see also Dean Milk Co.*, 340 U.S. at 354; *Southern Pac. Co. v. Ariz. ex rel. Sullivan*, 325 U.S. 761, 767-68 & n.2 (1945); *Nat’l Meat Ass’n*, 743 F.2d at 661 & n.3. Even the dissenting justices in *C & A Carbone*, who would have upheld the favoritism toward local entities in that case, agreed that no locality could “finance a public improvement . . . by transferring its cost to out-of-state economic interests.” *C & A Carbone*, 511 U.S. at 411 (Souter, J., dissenting).

Indeed, the reason that *tariffs* constitute the “paradigmatic Commerce Clause violation” is because, like the Ordinance, they collect revenue from interstate goods in order to alleviate local tax burdens. *West Lynn Creamery*, 512 U.S. at 203, *see also Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 575 (1997). Like a tariff, the Ordinance’s purpose is to have the cost of running local government programs—here, the cost and liability risks of the collection

program—paid for by unrepresented interstate actors, rather than through normal or special taxes or waste-disposal fees paid by local citizens and consumers.

Indeed, the Ordinance is even more problematic than a tariff for two reasons. First, although an impermissible tariff reduces the burden on local taxpayers, the exclusionary “cost of the tariff is also borne primarily by *local consumers*,” *West Lynn Creamery*, 512 U.S. at 203 (emphasis added), who must pay the higher price caused by the tariff. Here, by contrast, the Ordinance not only spares local taxpayers the costs of the collection programs, it also favors local consumers by prohibiting the imposition of local point-of-sale fees to recoup collection costs. *See supra* p. 9. Second, although tariffs solely impose *financial* costs on the interstate flow of goods, the Ordinance, as noted, imposes affirmative obligations and activities on Producers, requiring that they alter their business practices (from production to disposal) outside of Alameda and establish a presence in Alameda. Thus, the Ordinance’s burden and extra-territorial effect is even worse than that of a tariff.

b. For these reasons, it is quite clear that, if the Ordinance simply said on its face that collection obligations are triggered, like a tariff, by “*delivery*” of “covered drugs” into Alameda, this would have been an impermissible direct burden on the flow of interstate products. Alameda nevertheless argued below that, because the Ordinance facially says collection obligations are triggered if the

drug is “*sold or distributed*” within Alameda, the law’s 100% effect on medicines delivered from outside Alameda should be ignored. *See* Defendants’ Motion for Summary Judgment at 20-21, Tr. Dkt. 31. The district court accepted this argument, concluding that the Ordinance was unlike a tariff because a tariff “taxes goods imported from other States, but does not tax similar products produced in the State,” while the Ordinance would facially impose costs not just on drugs delivered from *outside* Alameda, but also for drugs produced and distributed *within* Alameda. Op. 10, ER 10 (quoting *West Lynn Creamery*, 512 U.S. at 193). But, again, it is *stipulated* that *all* covered drugs are delivered from outside Alameda, and *none* are distributed wholly within Alameda. (Even the less than 1% of Covered Drugs produced by the three Alameda-based manufacturers are first shipped outside of Alameda and then sent back into the County. *See* Stipulations ¶¶ 23, 24, ER 85.)

Consequently, the “practical effect” of the Ordinance is *precisely the same* as a law which, like a tariff, *explicitly* imposes take-back costs only on drugs delivered from outside of Alameda. Accordingly, the real world effect of the Ordinance is indistinguishable from a tariff or take-back law which facially imposed costs only on “goods imported from other [counties],” but did not impose them on “similar products” produced and distributed “in” the jurisdiction. Op. 10, ER 10 (internal quotation marks omitted). Under either law, the negative

economic costs attach only to goods delivered to Alameda, not to any goods distributed within Alameda.⁶

This is dispositive because, as this Court has repeatedly noted, the “Supreme Court has emphasized that the ‘practical effect’ of a challenged statute is ‘the critical inquiry’ in determining whether that statute constitutes direct regulation.” *S. D. Myers*, 253 F.3d at 467 (quoting *Beer Institute*, 491 U.S. at 336). For example, the Supreme Court in *Hunt v. Washington State Apple Advertising Commission* struck down a North Carolina law that prohibited certain types of product labeling on the ground that “the challenged statute has the practical effect of . . . burdening interstate sales of Washington apples.” *Hunt*, 432 U.S. 333, 350 (1977). Likewise, the Court in *C & A Carbone* invalidated a local measure requiring locally produced waste to be processed in a local transfer station. While

⁶ For the reasons identified in the text, the Ordinance also discriminates against interstate trade and so fails the second *per se* prohibition under the Commerce Clause. Under well-established precedent, the Ordinance has a proscribed “discriminatory effect” against the “flow of interstate” *products* into Alameda. See *NAOO*, 682 F.3d at 149-50 n.5 (explaining that “strict scrutiny” applies if the law has a “discriminatory effect” or a “discriminatory purpose” regardless of whether it evinces “facial discrimination”). The dormant Commerce Clause doctrine prohibits even facially neutral actions with the “practical effect” of burdening the flow of “interstate goods.” *Nat’l Ass’n of Optometrists & Opticians LensCrafters, Inc. v. Brown*, 567 F.3d 521, 525 (9th Cir. 2009). Here, the Ordinance has the “practical effect” of “discriminat[ing] against interstate commerce” by burdening virtually only goods that are delivered from outside the County. *S.D. Myers*, 253 F.3d at 446.

recognizing that the “ordinance may not in explicit terms seek to regulate interstate commerce, it does so nonetheless by its practical effect and design.” *C & A Carbone*, 511 U.S. at 394.

Thus, the “critical inquiry” for purposes of the direct burden prohibition is what the statute *does* in the real world, not what it *says* on its face. As the Supreme Court has frequently noted, if courts’ analysis of commerce burdens myopically focused only on the local statute’s *language*, rather than its practical effect, this would create a gaping hole in the dormant Commerce Clause which would be easily evaded by protectionist state laws. Under the formalistic regime embraced by the district court, the “Commerce Clause of itself imposes no limitations on state action . . . save for the rare instance where a state artlessly discloses an avowed purpose to discriminate against interstate goods.” *Dean Milk*, 340 U.S. at 354; *see Hunt*, 432 U.S. at 352-53.

Consequently, the Court has consistently invalidated laws if they have the *effect* of directly burdening or discriminating against interstate goods. Even the case that the district court relied on, *West Lynn Creamery*, itself condemned the law because it had an *effect* equivalent to a facially exclusionary tariff. Specifically, the Massachusetts law was invalidated because it was “*equivalent* to import or customs duties” and had “the same *effect* as a tariff,” since, “like an ordinary tariff, [it] is *effectively* imposed only on out-of-state products.” *West*

Lynn Creamery, 512 U.S. at 194-195 (emphasis added) (internal quotation marks omitted); *see also Cloverland-Green Spring Dairies, Inc. v. Penn. Milk Mktg. Bd.*, 298 F.3d 201, 211 (3d Cir. 2012) (The Commerce Clause forbids the “functional equivalent of a tariff.”).

In short, since “practical effect” is the “critical inquiry,” and since the Ordinance’s effect is indistinguishable from a law facially targeting goods delivered into the County, it is plain that the Ordinance is no more valid than a law containing such a facial burden on interstate commerce. If the “practical effect” test means *anything*, it must reach laws with effects *identical* to laws facially targeting delivery of interstate goods.

Moreover, even assuming the “practical effect” test did not directly invalidate the Ordinance, it would still be plainly impermissible because, *however* it is characterized, it inherently burdens the interstate market by imposing costs on the interstate manufacturers that clearly exceed, and are in addition to, the traditional local revenue burden that states may impose on products within their jurisdiction. That is, the dispositive difference between a permissible local sales tax and a paradigmatically impermissible tariff is that the former imposes a burden on the *sale* of products *within* the taxing jurisdiction, while the latter imposes economic burdens on those who produce and ship goods from *outside* the jurisdiction. Thus, a 2% tax on the local sale of goods is permitted, while a 2%

tariff on producers shipping goods into the jurisdiction is plainly improper. This is because, again, extracting revenues from local transactions at the end of the interstate distribution chain is acceptable, since it is an exercise of the local jurisdiction's traditional power over transactions within their borders and because the burden is borne by the local merchants and consumers engaging in that transaction. In contrast, taxing those higher up the distribution chain typically burdens foreign producers and shippers, impermissibly intrudes into the federal government's plenary control over the interstate market, and results in double taxation that is, by definition, disproportionate to the local jurisdiction's relationship to the goods sold in its community. *See Complete Auto Transit, Inc. v. Brady*, 430 U.S. 274, 279 (1977) (requiring local taxes to be, among other things, based on a nexus with the taxing jurisdiction and fairly apportioned). *See infra* p. 58.

Here, for example, Alameda has already taxed Producers' products sold in Alameda through its local sales tax. To then add the economic burden of the collection program's costs on top of this local tax necessarily impedes the flow of goods by extracting from the interstate market more than Alameda's fair and proportionate share of revenue from products with a nexus to Alameda, thereby shifting the costs of the collection program from Alameda taxpayers and

consumers to consumers in the national market. *See Complete Auto*, 430 U.S. at 279.

This rent seeking from the interstate market is particularly obvious because, as noted, the Ordinance expressly shields local consumers from the collection program's costs and because Alameda eschewed the traditional option of financing the collection programs through a special waste disposal fee attached to Alameda pharmaceutical sales. Alameda's unprecedented decision to exclusively impose the take-back program's financial and other burdens on pharmaceutical producers who are not involved in either sales or disposal of pharmaceuticals within Alameda is plainly a direct burden on interstate commerce—one that is fundamentally different from taxing the sale of products within the jurisdiction's borders.

* * *

In sum, while the Commerce Clause tolerates a local jurisdiction's *indirect* regulation and burdening of interstate commerce when they are exercising their traditional sovereignty over products distributed within their borders, because outlawing such burdens would strip states of the police power left to them under the Commerce Clause, the Clause forbids direct regulation or burdening of the interstate flow of goods. Here, the Ordinance (1) is not an exercise of the police power; (2) does not regulate or tax the sale of products within its jurisdiction; (3) uses the presence of the interstate product in its jurisdiction as the hook to

require out-of-state producers of those products to conduct local waste disposal; (4) imposes regulatory and financial burdens on the flow of those collection-triggering medicines into Alameda; and (5) imposes an affirmative *disposal* obligation in Alameda that has no nexus to the Producers' out-of-state *manufacturing* activity. Thus, the Ordinance's waste disposal mandate has *no* connection to the local police power regulatory sphere left to the states under the Commerce Clause and is *solely* based on an extraordinarily attenuated interstate connection to the conscripted Producers. It therefore constitutes impermissibly direct regulation of interstate commerce with directly burdensome effects, not an exercise of the police power with incidental effects on interstate commerce.

B. The Ordinance Has The Impermissible Primary Purpose of Burdening Interstate Commerce For Local Advantage.

The Ordinance also is plainly invalid under this Court's specific formulations implementing the *per se* prohibition against direct regulation and burdening of interstate commerce. As noted, under this Court's precedent, state laws are *per se* invalid under the direct regulation/burden test if their central or primary purpose is to regulate commerce, usually for the benefit of local interests. *See Kleenwell*, 48 F.3d at 395-96. For the reasons already stated, the Ordinance plainly flunks this test since its only purpose is to impose collection costs and responsibilities on the interstate market to benefit the local government and

taxpayers by relieving them of this burden—indeed, this is the *avowed* and *consistently articulated* purpose of the Ordinance.

1. The Ordinance’s legislative history makes crystal clear that Alameda chose to fund its pharmaceutical collection program by regulating interstate producers with the precise goal of shifting to them the regulatory costs that would otherwise be borne by local taxpayers. *See Hunt*, 432 U.S. at 352 (discussing “indications in the record” that a State’s “discriminatory impact on interstate commerce was not an unintended byproduct”). As detailed above, see *supra* pp. 4-6, almost every comment introduced by the Ordinance’s sponsor, most from governmental sources, emphasized that the Ordinance would shift costs away from local taxpayers. For example, a number of letters said that “the costs of [pharmaceutical collection] should not fall on local government.” *Supra* pp. 5-6. Similarly, a representative of the Department noted at a Board meeting that the County’s existing collection sites “are paid for by taxpayers or ratepayers,” and argued that “the cost shouldn’t fall on local government.” *Supra* pp. 4-6. And Nathan A. Miley, the Ordinance’s principal sponsor and President of the Board of Supervisors, candidly stated that the only thing “wrong” with a “publicly-funded

[collection] program” in Alameda “is that the taxpayers pay for it.” *See supra* pp. 5-6.⁷

Moreover, in this litigation, Alameda’s *defense* of the Ordinance is that it preserves the County’s own “sparse resources” by transferring regulatory costs to parties that “benefit” from the sale of prescription pharmaceuticals. Defendants’ Motion for Summary Judgment at 7, Tr. Dkt. 31. Thus, the County has conceded that the only relevant aspect of the Ordinance—its implementation of the philosophy of “Extended Producer Responsibility”—was motivated by the desire to shift regulatory costs onto out-of-Alameda producers. If Alameda had wanted to *neutrally* impose collection costs on those “benefitting” from Alameda

⁷ The Ordinance’s unconstitutional gerrymander and rent-seeking purpose extends so far that it violates the third *per se* dormant Commerce Clause rule by favoring local interests over their out-of-County counterparts. The Ordinance’s local favoritism is most obvious in its express prohibition on point-of-sale fees to recoup compliance costs. § 6.53.040.B.3. The only conceivable reason to adopt this rule is to eliminate the most feasible means of redistributing the Ordinance’s costs back to the Alameda consumers, thereby shifting those costs to non-Alameda consumers. As the Court explained in *Camps Newfound*, 520 U.S. 564, “[e]conomic protectionism is not limited to attempts to convey advantages on local merchants; it may include attempts to give local consumers an advantage over consumers in other States.” *Id.* at 577-78. Here, the Ordinance ensures that the burden of the County’s local pharmaceutical collection efforts will be “felt almost entirely” by pharmaceutical consumers nationwide. *Id.* at 581. Moreover, in-County and out-of-County consumers are “substantially similar” to one another and so offer, under any reasonable approach, an appropriate test for local favoritism. Finally, the Ordinance facially favors local pharmacies over the foreign Producers by exempting them from any drug-collection responsibilities and costs.

pharmaceutical sales, it would have done so in the time-honored manner by which local governments impose the cost of regulation on those involved in the relevant activity—namely, by imposing a tax or fee on the sale of the regulated product. But that traditional, neutral method would have affected *local* actors because it would burden local companies and consumers. Alameda rejected that traditional scheme for a conscious gerrymander that singles out for *all* collection costs the only “benefitted” entities that are almost exclusively located outside Alameda County.

2. Needless to say, such efforts to benefit local taxpayers by cost-shifting to interstate businesses and consumers is obviously impermissible because, as noted, such cost-shifting was the principal evil addressed by the Commerce Clause, and because tariffs are impermissible for that reason. *See supra* pp. 18-20. Indeed, the Supreme Court has developed a particular line of Commerce Clause analysis condemning local laws that impose taxes on interstate actors that are disproportionate to their products’ presence in the taxing jurisdiction, precisely to prevent local governments from reducing their own tax burdens at the expense of interstate market participants. *See Complete Auto*, 430 U.S. at 279; *infra* p. 53.

Moreover, the Ordinance benefits local interests not only by relieving local entities of any *tax* burden to finance the collection program, but also by carefully and scrupulously relieving those local entities of any *non-tax* burdens related to

that program. First, as noted, it expressly exempts local consumers from any point-of-sale fee related to collection and disposal costs, a restriction that serves no purpose other than seeking to insure that this program, designed to exclusively benefit Alameda residents, will be exclusively paid for by consumers outside of Alameda. Second, although the articulated rationale for imposing collection costs on interstate producers is that those who “benefit” from pharmaceutical *sales* should pay for pharmaceutical *disposal*, the Ordinance exempts the two local entities that also plainly benefit from pharmaceutical sales and contribute to the pharmaceutical disposal “problem” purportedly necessitating the collection program. The local Alameda pharmacies that directly benefit economically from the local drug sales are expressly exempted from the collection responsibilities borne by interstate actors, *see supra* p. 6, and the consumers who medically benefit are exempt from any fees to pay for such programs. This is particularly illogical because these local consumers stand to directly benefit from the Ordinance’s drug disposal program and contribute to the improper disposal which purportedly requires that program.

3. Moreover, the Ordinance indisputably imposes a substantial *burden* on interstate commerce given the millions of dollars needed to establish a joint collection entity and conduct collection programs, and to either insure against or absorb the obvious liability risks of a program requiring the public storage and

disposal of controlled substances. (Indeed, the financial burden is conclusively established because the Ordinance *shifts* that burden—if it were a *de minimis* cost compared to Alameda’s roughly \$2.5 billion dollar annual budget, shifting it to Appellants would serve no real purpose.)

This regulatory and financial burden is particularly evident when it is assessed, as it must be, based on the effect that would result if every jurisdiction adopted similar measures. *See, e.g., Beer Inst.*, 491 U.S. at 336-37 (“[T]he practical effect of the statute must be evaluated not only by considering the consequences of the statute itself, but also by considering . . . what effect would arise if not one, but many or every, State adopted similar legislation.”); *S.D. Myers*, 253 F.3d at 467 (same); *NAOO*, 682 F.3d at 1149 n.5 (same). Thus, the relevant question is the interstate commerce burden that would result if all of the Nation’s 3,000 counties adopted similar measures. Widespread adoption of Ordinance-like laws would “stifle” the interstate market by making interstate businesses liable for the full costs of running waste-disposal programs in every county where their products are sold. *See Edgar v. Mite Corp.*, 457 U.S. 624, 642 (1982) (plurality opinion) (“[I]f Illinois may impose such regulations, so may other States; and interstate commerce . . . would be thoroughly stifled.”); *see also Beer Institute*, 491 U.S. at 337; *Brown-Forman*, 476 U.S. at 582; *S.D. Myers*, 253 F.3d at 470; *West v.*

Kan. Natural Gas Co., 221 U.S. 229, 255 (1911) (“[E]mbargo may be retaliated by embargo, and commerce will be halted at state lines.”).

Here, there can be little doubt that, if upheld, Ordinance-like measures would rapidly multiply since it is always attractive to get something for nothing, particularly given the severe budgetary constraints currently faced by most states and counties. Indeed, a nearly identical Ordinance concerning prescription drugs has already been enacted by King County (containing Seattle), Washington;⁸ and, according to Alameda, the California legislature has adopted and is considering similar “producer responsibility” measures for other industries. *See* Defendants’ Motion for Summary Judgment at 6, Tr. Dkt. 31.

Also, the other reason that the Supreme Court insists on examining the multiplying effect of a particular jurisdiction’s law is because the Commerce Clause was meant to avert the kind of “rival, conflicting and angry regulations” that can be touched off by even the most modest regulation of interstate trade. *H.P. Hood & Sons*, 336 U.S. at 534 (internal quotation marks omitted); *see also C & A Carbone*, 511 U.S. at 390 (noting “those jealousies and retaliatory measures the Constitution was currently designed to prevent”); *Oregon Waste*, 511 U.S. at 98; *Baldwin v. G.A.F. Seelig*, 294 U.S. 511, 522 (1935). Consistent with the

⁸ *See* King County Secure Medicine Return Rule & Regulation, *available at* <http://www.kingcounty.gov/healthservices/health/BOH/MedicineTakeback.aspx>

Framers' experiences with retaliatory tariffs, covered producers must be concerned not just with the burdens imposed by Alameda County, but also with the threat of hundreds of distinct collection mandates nationwide, whose combined effect would stifle interstate commerce. *See Camps Newfound*, 520 U.S. at 577; *Edgar*, 457 U.S. at 642 (plurality opinion) (“[I]f Illinois may impose such regulations, so may other States; and interstate commerce . . . would be thoroughly stifled.”); *Kan. Natural Gas Co.*, 221 U.S. at 255.

Unused pharmaceutical-collection programs are quite likely to induce these retaliatory efforts, particularly since, under the district court's and Appellees' myopic “facial” analysis, counties would have free reign to impose collection programs on products where there are *no* producers of the product in the county (and thus no facial burden on *inter-county* delivery of goods and no facial discrimination against interstate commerce). Accordingly, each state and county could choose to impose collection requirements on every product produced *outside* its jurisdiction, without burdening any in-state entities to whom they are politically accountable—the exact scenario where, as this Court has frequently noted, they have the *greatest* incentive to engage in measures disrupting interstate commerce. *See supra* pp. 30-31.

For example, all states or counties which produce little or no wine, computers or film could require California vintners to engage in glass bottle

recycling, or Silicon Valley computer manufactures to dispose of all used computers, or Hollywood film studios to clean up all local movie theaters or dispose of all used film stock. Yet the Commerce Clause exists precisely in order to prevent localities from “rendering others tributary to them by commercial regulations.” THE FEDERALIST No. 7, at 40 (Hamilton). And the Framers understood that this required particular vigilance regarding laws targeting *other* states’ products. Accordingly, during the Founding era, they plainly would have condemned an effort by New England states to impose take-back or similar financial burdens on “cotton” because such measures would clearly be targeting the Southern states’ agricultural product. Yet, under the district court’s formalism, such trade-war inducing measures are perfectly fine, because they do not *facially* exempt the non-existent “New England cotton growers” from this burden.

C. The Ordinance Impermissibly Affects Transactions Across County Lines.

As this Court has explained, “[d]irect regulation occurs when a state law directly affects transactions that [i] take place across [county] lines or [ii] entirely outside of the [County’s] borders.” *S.D. Myers*, 253 F.3d at 467 (internal quotation marks omitted). The Ordinance violates both of those requirements.

1. *Across County Lines.* For the reasons previously stated, direct regulation can be established by showing that the *practical effect* of a local measure is to regulate the *delivery* of products across state or county lines. Here,

as noted, the Ordinance “directly affects” *only* drugs coming “across the [County’s] lines,” and is, therefore just as invalid as a law that *explicitly* imposed regulatory burdens on *delivery* of medicines *across* those lines. *See supra* pp. 35-36. (Indeed, the Ordinance’s third coverage criterion *overtly* targets delivery of the medicines across the County lines—namely, “the Person who *brings* the Covered Drug *into Alameda County* for sale or distribution,” § 6.53.030.14 (emphases added).) Thus, under the “practical effect” doctrine, the Ordinance is invalid because it effectively applies only to interstate goods.

2. *Outside The County’s Borders.* The Ordinance also reaches people and entities with *no* presence in Alameda County and then forces those persons to come *into* the County to perform a waste disposal function. Entities without a single sales person in Alameda County or a single transaction in the County must now start collecting unused medicines in the County. (Indeed, the Ordinance’s reach is so unbounded as to violate the Due Process Clause by imposing obligations on Producers who lack any minimum contact with Alameda County. *See J. McIntyre Mach., Ltd. v. Nicastro*, 131 S. Ct. 2780 (2011).)

It is axiomatic that local laws with an “extra-territorial effect” “exceed[] the inherent limits of the enacting State’s authority and [are] invalid regardless of whether the statute’s extraterritorial reach was intended by the legislature,” *Beer Institute*, 491 U.S. at 336; *see also Brown-Forman*, 476 U.S. at 582. The

Ordinance violates this basic command because it requires pharmaceutical producers to enter into an entirely new business practice—waste disposal—and to enter Alameda to perform it. Needless to say, localities cannot condition the delivery of interstate goods on having the foreign, interstate supplier enter the locality to perform the locality's own public functions. Although there is no case directly on point since, prior to the Ordinance, no local government attempted to so directly conscript interstate actors, the Ordinance's extra-territorial effect (and purpose) far exceed that of the extra-territorial laws invalidated by the Supreme Court.

In *Beer Institute*, for example, New York passed a law establishing the maximum price beer sellers could charge in New York. *Beer Institute*, 491 U.S. at 336; *see also Baldwin*, 294 U.S. 511. This purely *intra-state* regulation of *New York sales* was nonetheless invalid because, in conjunction with laws and market practices in neighboring states, it had a downstream effect on the prices charged in those bordering states. *Beer Institute*, 491 U.S. at 336-37. This unintended, extra-territorial effect on *prices* obviously pales in comparison to the Ordinance's purposeful and direct regulation of out-of-state activities, and the coercion to enter Alameda. New York obviously could not have conditioned all New York beer sales on the beer companies establishing *breweries* in New York. But the

Ordinance is even worse because, unlike the hypothetical local *brewery* requirement, it mandates that Producers enter into a *new* industry—*disposal*.

Similarly, in *Hunt*, the North Carolina law did not regulate the sales price of apples, or change the nature of the affected producers' business activities, but was nonetheless an invalid restriction on interstate commerce, notwithstanding the Court's assumption that it was "for the declared purpose of protecting consumers from deception and fraud in the marketplace," 432 U.S. at 353; *id.* at 352 ("[W]e need not ascribe an economic protection motive to the North Carolina Legislature."). This was because North Carolina's consumer disclosure requirement for the labeling of apples *sold in North Carolina* had the indirect effect of requiring Washington apple-growers to change the *labeling* they wanted to affix to apple cartons in Washington. This relatively minor out-of-state effect and cost was nonetheless impermissible because it was not "very attractive to the industry" in Washington, which asserted a "preference" to retain their own labeling, rather than acquiesce to North Carolina's labeling. *Id.* at 338, 351.

Likewise, the Nevada law in *NCAA* did not command collegiate athletic organizations to undertake *any* conduct outside of Nevada. To the contrary, the law in *NCAA* regulated only the *manner* in which the NCAA would conduct discipline proceedings *within Nevada*, by requiring certain basic due process protections. 10 F.3d at 637. This *wholly intra-state* due process requirement was

nonetheless invalid because other states might also require similar or different due process minima, which the NCAA would have to accommodate. *Id.* at 639. These relatively minimal adjustments to proceedings and labels do not remotely compare to the Ordinance's dictates.

The district court rejected the foregoing arguments because “[n]othing in the Ordinance will require, as a practical matter, any producer to alter its manner of doing business in any jurisdiction outside of Alameda County.” Op. 9, ER 9. The district court apparently meant that the Ordinance does not by its terms require pharmaceutical collection efforts outside of Alameda County itself. *See id.* (explaining that “producers will be free to use programs that they may already be using elsewhere, provided they meet the standards of the Ordinance”). But the Ordinance will directly affect transactions that take place outside Alameda by imposing a regulatory regime on pharmaceutical producers who have never so much as set foot in Alameda County. Under the Commerce Clause, a local measure cannot regulate an extra-jurisdictional entity simply because that entity has exercised its constitutional right to engage in interstate commerce. Yet that is just what the Ordinance purports to do.

In addition to the magnitude of its burden, the Ordinance is also worse than the extra-territorial laws previously struck down because of the *scope* of its *coverage*. The Ordinance directly regulates producers that have never engaged in a

transaction anywhere near Alameda. The Ordinance applies to a “Producer whose Covered Drug is sold or distributed in Alameda County.” § 6.53.040.A. Thus, producers are subject to the Ordinance if some *other entity* “sell[s], offer[s] for sale, or distribute[s] prescription drugs in Alameda County.” And, as the uncontested facts in this case demonstrate, producers themselves rarely engage in the Alameda drug sales or distribution that trigger collection responsibilities. Stipulation ¶ 18, ER 84. Rather, producers almost exclusively contract with *wholesalers* and large retail chains, and they in turn “sell, offer for sale, or distribute prescription drugs in Alameda County.”

The Ordinance thus plainly applies to Producers who do not “operate” or have a “physical presence” in the County. Yet the dormant Commerce Clause typically insists that only entities with a “physical presence” in the locality may be subjected even to local taxes, much less to the burdensome regulation here. *See Quill*, 504 U.S. at 311, 312. Indeed, the Ordinance applies to Producers regardless of whether they intend or could even foresee that their products will make their way to Alameda County in the stream of commerce. *But see J. McIntyre*, 131 S. Ct. 2780. Thus, the Ordinance would have impermissible extraterritorial effects even if it is viewed as a traditional mode of local regulation.

III. The District Court Erred In Upholding The Ordinance's Direct Burden On Interstate Goods Because It Was Not Accompanied By Local Company Favoritism

There is no dispute that the Ordinance has a direct and impermissibly burdensome effect on the flow of goods in interstate commerce. Yet the district court did not even *discuss* the central purpose requirement or the prohibition on local regulation of transactions that cross jurisdictional lines. Instead, the district court rejected Appellants' direct regulation argument for the same reason it disposed of Appellants' challenge under the other two *per se* prongs: the Ordinance does not discriminate in favor of Alameda County *corporations*.⁹ In other words, the district court rejected Appellants' "direct regulation" argument entirely on the ground that the Ordinance did not violate the third *per se* category relating to favoritism for "in-state economic interests." But the district court's

⁹ First, the district court emphasized that "[n]othing in the structure of the Ordinance targets *producers* on the basis of their *location*" and that Alameda County has not imposed burdens on producers simply "because they are out-of-state actors." Op. 9, ER 9. The district court then went on to distinguish the Ordinance from tariffs on the ground that a tariff "benefits local producers by burdening their out-of-state competitors," whereas the Ordinance did not. *Id.* at 10, ER 10 (internal quotation marks omitted). And, finally, the district court dismissed as irrelevant "the happenstance that most producers of prescription drugs are located outside Alameda County," since that fact "is insufficient to transform what is fundamentally a local measure into one that could be found to burden interstate commerce impermissibly." *Id.*

conclusion that local *company* favoritism is the only way to impermissibly burden interstate commerce is a flawed and improper application of the Commerce Clause.

The Commerce Clause protects interstate *commerce*, meaning the flow of goods in interstate trade. As this Court has repeatedly said, both times with emphasis: “The decision of whether a nondiscriminatory regulation nevertheless significantly burdens interstate commerce depends ‘on the interstate *flow of goods*, not on where the retailers were incorporated.’” *Yakima Valley Mem’l Hosp. v. Washington State Dep’t of Health*, 731 F.3d 843, 847 (9th Cir. 2013) (quoting *NAOO*, 682 F.3d at 1153 (emphasis in original)). The district court flipped this truism on its head by holding that dormant Commerce Clause violations turn on how *companies* located in *Alameda* are treated relative to outsiders, even if the Ordinance (as is undisputed) disrupts the “interstate *flow of goods*.” So making “local company discriminatory preferences” the *sine qua non* of a Commerce Clause violation is contrary to the Constitution, common sense and binding precedent.

The plain language of the Constitution protects “Commerce . . . among the . . . states,” not “companies from out of state”—the Commerce Clause is not an Equal Protection Clause for foreign companies. Consequently, dormant Commerce Clause cases naturally hold that discrimination against “some interstate *companies* does not, by itself, establish a claim of discrimination against interstate

commerce” *Exxon Corp. v. Governor of Maryland*, 437 U.S. 117, 126 (1978) (emphases added)). A regulation which had “no demonstrable effect whatsoever on the interstate flow of goods,” *id.* at 126 n.16 (emphasis added), is not invalid simply because the regulated companies are disproportionately located outside the state. *See also NAOO*, 682 F.3d at 1153 (“[T]he *Exxon* Court’s decision turned on the interstate *flow of goods*, not on where the retailers were incorporated, what the out-of-state market shares of sales and profits were” (emphasis in original)). But the district court erroneously took those holdings to mean that there can be no violation under the Commerce Clause, *even* if it affects the interstate flow of goods, *unless* the local regulation burdens out-of-county corporations by favoring in-county producers. Under the district court’s flawed reasoning, Alameda County is free to harm what the Commerce Clause protects (interstate commerce) unless it also harms what the Commerce Clause does *not* protect (out-of-state companies).

But, as *Exxon* and *NAOO* make clear, the *only* reason that the cases invalidate laws favoring in-state companies is because doing so can affect the flow of interstate products. For example, when a state subjects out-of-state companies to burdens or taxes not imposed on local companies, this skews the flow of goods by giving the locally produced good a price or similar advantage. *Hunt*, 432 U.S. 333; *Dean Milk*, 340 U.S. 349.

Discriminating against out-of-state companies, however, is only *one possible* way of burdening the flow of interstate commerce—and binding precedent establishes that other measures restricting the stream of interstate products is impermissible, regardless of whether they favor local companies. Most obviously, the Supreme Court has invalidated local laws that burdened the flow of goods, while actually *disadvantaging* local industry. In *Hughes v. Oklahoma*, 441 U.S. 322, 325 (1979), for example, the Court invalidated a local law prohibiting the *export* of minnows out of Oklahoma. That export prohibition obviously could not *protect* any local industry; its restriction on minnow exports clearly fell harder on local Oklahoma companies wanting to engage in such exports. But the law was still unconstitutional because it obstructed the *flow of interstate commerce*.

In many other cases, restricting the flow of interstate goods was condemned absent any protection of local *companies* and, indeed, even though local companies were the parties challenging the regulation. In *Chemical Waste Management, Inc. v. Hunt*, for example, an Alabama law's burdens fell on an in-state business—namely, the plaintiff Alabama waste developer. 504 U.S. 334, 348 (1992). Likewise, *Philadelphia v. New Jersey* held that a New Jersey law discriminated against interstate commerce even though it equally disadvantaged “New Jersey commercial interests,” 437 U.S. 617, 626-27 (1978); and *C & A Carbone* held that local laws can be invalid even when “in-state or in-town [businesses] are also

covered” by the offending law. *C & A Carbone*, 511 U.S. at 391. As these cases demonstrate, “a burden imposed by a State upon interstate commerce is not to be sustained simply because the statute imposing it applies alike to . . . the people of the State enacting such statute.” *Brimmer v. Rebman*, 138 U.S. 78, 83 (1891).

Thus, binding precedent establishes that where, as here, the challenged law burdens interstate products, there is no need to show that it favors in-state companies. Indeed, precedent establishes that disrupting the flow of goods in order to reduce the local tax burden—the avowed purpose of the Ordinance—is impermissible regardless of whether it favors local companies. Local taxes are permissible under the Commerce Clause only if they are, among other things, “applied to an activity with a substantial nexus with the taxing State,” and “fairly apportioned” among states. *Complete Auto Transit*, 430 U.S. at 279. These independent requirements are, of course, designed to prevent localities from exacting more than their “fair share” of the benefits associated with interstate commerce and thus imposing a disproportionate financial burden on the flow of interstate products. *Oklahoma Tax Comm’n v. Jefferson Lines, Inc.*, 514 U.S. 175, 184 (1995); *see also Commonwealth Edison Co. v. Montana*, 453 U.S. 609, 616 (1981). In short, the *Complete Auto* line of cases establishes that the dormant Commerce Clause condemns efforts by local governments to impose an undue tax burden on interstate goods regardless of how the tax treats local companies. Thus,

excessive financial impositions on the interstate market to reduce local tax burdens is, standing alone, forbidden, even if not accompanied by discrimination preferring native companies.¹⁰

Thus, the district court's holding that the dormant Commerce Clause cannot be violated absent local company favoritism is contrary to both the Constitution's language and binding precedent. It would also create a gaping hole in the Commerce Clause's protections. If the district court's analysis were correct, then the dormant Commerce Clause would give carte blanche to impose financial or other burdens when there are *no* affected producers in the county to favor. A state or county with no oil producers or computer manufacturers could finance all regulation of those products through "take-back" or similar financial burdens, and this burdening of interstate traffic would be immune from scrutiny under the court below's view, because there would be no local producers to overtly favor. Thus,

¹⁰ The Ordinance clearly fails the fair apportionment requirement, because the costs it imposes are not remotely correlated with, or measured by, the Producer's volume of Alameda *sales*. Moreover, the Ordinance requires *every* Producer—even those with minimal Alameda sales—to dispose of *all* unwanted medicines. Also, many medicines in Alameda County were not even sold there, but rather were brought into the jurisdiction by consumers. And the producers that made some medicines might no longer exist. Thus, far from taking its "fair share," the County has imposed a burden that is "out of all appropriate proportions to the business transacted" in the County, creating "a grossly distorted result." *Oklahoma Tax*, 514 U.S. at 185, 195-96 (internal quotation marks and citations omitted); *see also Container Corp. of Am. v. Franchise Tax Bd.*, 463 U.S. 159, 169-70 (1983).

under the district court's conception of the Commerce Clause, all jurisdictions have unfettered license to impose onerous burdens on all purely *foreign* industries. But, as noted, the seminal purpose of the Commerce Clause was to prevent states from relieving their own tax burdens by exploiting industries located in *other* states, since it always preferable to coerce monies out of unrepresented foreigners than one's own voters. *See, e.g., Conservation Force*, 301 F.3d at 998.

IV. The Ordinance Imposes Impermissibly Excessive Burdens On Interstate Commerce

Assuming *arguendo* that the balancing test of *Pike*, 397 U.S. at 142, governs this case, Appellants would still prevail. As the Supreme Court has explained, “the extent of the burden that will be tolerated will of course depend” not just “on the nature of the local interest involved,” but also “on whether it could be promoted as well with a lesser impact on interstate activities.” *Id.*; *see also Hunt*, 432 U.S. at 354. Here, the County has never disputed that its pharmaceutical-collection efforts would achieve precisely the same effects if performed by the County and financed by a local waste-disposal fee, rather than conducted and paid for by Appellants. And the County cannot dispute that the Ordinance imposes some burdens on pharmaceutical producers engaged in interstate commerce. *See* Stipulations ¶¶ 17, 24, 26-27, ER 84-85. A regulation that yields no public benefits while imposing burdens on interstate commerce is “clearly excessive.” *Pike*, 397 U.S. at 142. Because Alameda County “has imposed this burden without any significant

countervailing safety interest, its [Ordinance] violates the Commerce Clause.” *Kassel*, 450 U.S. at 678-79 (plurality opinion).

The district court rejected the foregoing reasoning based on a legal error. According to the district court: “Arguing that an alternative regime would have no burden on interstate commerce does not establish that the minimal burden this Ordinance arguably imposes on interstate commerce ‘clearly exceeds the local benefits.’” Op. 10, ER 10. Thus, the district court appears to believe that even *purposeless* burdens on interstate commerce are permissible, provided that they are sufficiently small. But, again, the Supreme Court has been clear that burdens on interstate commerce must be affirmatively justified by countervailing advantages that could not otherwise be attained. *Pike*, 397 U.S. at 142; *Kassel*, 450 U.S. at 678-79 (plurality opinion). Therefore, the critical question is whether legitimate benefits stem from the County’s decision to *shift the cost* of local collection efforts onto private parties engaged in interstate trade. The County’s decision to forgo conventional regulatory approaches in favor of burdening interstate commerce is therefore indefensible. *See Kassel*, 450 U.S. at 678-79 (plurality opinion).

CONCLUSION

For the forgoing reasons, Appellants respectfully requests that this Court reverse the District Court.

Dated: November 15, 2013

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C), the undersigned certifies that the attached opening brief is proportionally spaced, using a typeface of 14 points and—exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(a)(7)(B)(iii)—contains 13,849 words. As permitted by Fed. R. App. P. 32(a)(7)(C), in making this declaration, the undersigned has relied upon the word count of the word-processing system used to prepare the attached brief.

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STATEMENT OF RELATED CASES

Pursuant to Cir. Rule 28-2.6, Appellants state that:

- (a) there is no appeal that arises out of the same case (or any consolidated case) in the district court;
- (b) no appeal that concerns the case being briefed was previously taken to this Court;
- (c) They are unaware of any case that raises the same or closely related issues that are on appeal to this Court; and
- (d) They are unaware of any case that is on appeal to this Court and which involves the same transaction or event at issue in this case.

CERTIFICATE OF SERVICE

I hereby certify that on this 15th of November, 2013, on behalf of Plaintiffs-Appellants, I electronically filed the foregoing document with the Clerk of the United States Court of Appeals for the Ninth Circuit by using the CM/ECF system.

I further certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: November 15, 2013

Respectfully submitted:

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